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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/501,640	07/15/2004	William P Dankulich	20971P	2474

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/501,640	DANKULICH ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-37,39,40,45 and 46* is/are rejected.

7)☒ Claim(s) *38 and 41-44* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *10/12/04, 1/18/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Applicant's remarks with regard to claims 21-22 have been considered, and are found persuasive. Accordingly, claims 21-22 are examined along with claims 15-20, 23-46.

Applicant's election with traverse of the invention of Group II, claims 15-20, 23-46, and the specie, 17β-hydroxy-16-(pyrimidin-5-ylmethylidene)-4-methyl-4-aza-5α-androst-1-en-3-one, in the reply filed on May 6, 2008 is acknowledged. However, because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

The requirement is still deemed proper and is therefore made FINAL.

Claims 15-46 have been examined to the extent they read on the elected invention and specie.

As the elected specie, 17β-hydroxy-16-(pyrimidin-5-ylmethylidene)-4-methyl-4-aza-5α-androst-1-en-3-one, is found free of art, the search is extended to all of the compounds of formula I.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-32 provide for the use of the compounds herein claimed, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 30-32 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claims 23-27, 29, and 33-34 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The limitations "estrogen derivative", "progestin derivative", “parathyroid hormone or analog”, “an inhibitor of BMP antagonism”, “prostaglandin derivative”, “vitamin D derivative”, “vitamin K derivative” recited in claims 23-27, 29, 33-34 render the claims indefinite because it is not clear what compounds are encompassed by the claims. The metes and bounds of the claims are therefore not clear. For example, PTH “partial sequences”, recited in claim 24, is not clear what sequence be encompassed by such limitations.

Claims 23-27, 29, and 33-34 contain the trademark/trade name “CI-680, CI-628 … U-100A”, “EM-800”, EM-652, TSE 424”, “EB1089”, “KH1060”, ED71”. Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe various secondary compounds and, accordingly, the identification/description is indefinite.

Claim 33 recites the limitation "bone-strengthening agent" in line 1. There is insufficient antecedent basis for this limitation in the claim.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 15-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the

invention. In the instant case, the specification fails to provide sufficient information in order for one skilled in the art to practice the herein claimed invention.

Ex parte Forman (230 USPQ 546, BdPatApp & Int.) and *In re Wands* (858 F.2d 731, 8 USPQ2d 1400, 1404, Fed. Cir. 1988) provide several factors in determining whether the specification of an application allows the skilled artisan to practice the invention without undue experimentation. Having said factors in mind, the instant specification fails to reasonably provide enablement for methods of preventing the claimed condition. Specifically, the recitation of "preventing conditions in a subject…condition is selected from a group consisting of osteoporosis, osteopenia, sarcopenia, and frailty" in the instant claims 15 and 19, direct the claims to methods of preventing a pathological condition. However, the specification fails to properly enable such methods.

In the instant case, the burden of enabling for preventing the formation of osteoporosis, osteopenia, sarcopenia, and frailty requires appropriate screening testing, subsequent data compilation, and finally appropriate data analysis, to assess and properly enable one skill in the art whether wrinkles are prevented from formation in a patient. For example, the specification must provide adequate guidance whether osteoporosis, osteopenia, sarcopenia, and frailty can be prevented from forming in a patient or in this case, a mammal, once the composition is administered to a subject susceptible to develop osteoporosis, osteopenia, sarcopenia, and frailty.

Moreover, the specification must provide direct evidence associating the claimed prevention to the composition applied. The burden of showing preventative properties

is greater than that of enabling a treatment, because one of ordinary skill in the art must not only show competent screening of those subjects susceptible to such conditions, but also show that the efficacy of a preventative method is directly caused by applying or administering the instantly claimed composition to the susceptible subjects.

In this case, there is no teaching for screening methods identifying susceptible subjects nor is there any direct evidence of efficacy establishing a preventative property associated with the claimed composition. Furthermore, the state of the prior art concerning methods of absolute preventing the formation of osteoporosis, osteopenia, sarcopenia, and frailty is not well described. Accordingly, undue experimentation is necessary to determine screening and testing protocols to demonstrate the efficacy of the presently claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 15-37, 39-40, and 45-46 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO98/25622 (‘622), WO98/25623 (‘623), US 5,945,412 (‘412) in view of US 5,693,809 (‘809).

‘622 teaches 5-α reductase inhibitors, , which are structurally similar to the herein claimed compounds, with optional secondary compounds are useful in treating

osteoporosis (See page 19, line 25 – page 25, line 24), The secondary compounds can be the herein claimed estrogen derivatives and bisphosphonates.

'623 teaches 5-α reductase inhibitor finesteride with optional secondary compounds are useful in treating osteoporosis (See page 10 – page 19 for example), The secondary compounds can be the herein claimed estrogen derivatives and bisphosphonates such as alendronate (See page 14, line 23 for example).

'412 teaches 5-α reductase inhibitor compounds, which are structurally similar to the herein claimed compounds, with optional secondary compounds are useful in treating osteoporosis (See col. 3, line 4 – line 29), The secondary compounds can be the herein claimed estrogen derivatives and bisphosphonates (see col. 16, line 36 – col. 19, line 58).

The references do not expressly teach the herein claimed compounds of formula I with optional alendronate or other secondary compounds herein as useful in treating osteoporosis.

'809 teaches the herein claimed aza-androstene compounds when A is OH (see formula IIA), Z is α-hydrogen and β-hydrogen, T1 and T2 is hydrogen and alkyl respectively (See col. 2, line 50 – col. 4, line 15, for example). '809 also teaches the compounds are 5α-reductase inhibitors (See col. 2, lines 37-45).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the herein claimed 5-α-reductase inhibitors with optional alendronate or other secondary compounds herein in a method and composition of treating osteoporosis.

One of ordinary skill in the art would have been motivated to employ the herein claimed 5-α-reductase inhibitors with optional alendronate or other secondary compounds herein in a method and composition of treating osteoporosis. Since the herein claimed compounds are known 5-α-reductase inhibitors and various 5-α-reductase inhibitors that are structurally similar to the herein claimed ocmpounds are known to be useful in treating osteoporosis. Therefore, employing any known 5-α-reductase inhibitors, including those are taught in '809, with optional alendronate or other secondary compounds herein in a method and composition of treating osteoporosis would be reasonably expected to be effective.

Allowable Subject Matter

Claims 39 and 41-44 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon - Fri from 9:00 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617

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